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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,326	10/14/2003	Gary Weller	514362001200	8249

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EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/686,326	Applicant(s) WELLER ET AL.	
	Examiner Julian W. Woo	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50-65 is/are allowed.
- 6) ☒ Claim(s) 1,2,6,10,13,22,23,26,33,34,66,68,69,71,72 is/are rejected.
- 7) ☒ Claim(s) 3-5,7-9,11,12,14-21,24,25,27-32,35-49,67,70 and 73-78 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/03, 2/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 6, 10, 13, 22, 23, 26, 33, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (5,542,949). Yoon discloses, in the figures, a system having a tissue acquisition device with a curved (i.e., cylindrical), elongate main body (89) defining a main lumen therethrough, where the distal end of the acquisition device is adapted to acquire tissue, and a tissue fixation device having an articulatable cartridge (50) adapted to be advanced through the main lumen (i.e., movable within the lumen during loading and withdrawal of the cartridge), where the device comprises two opposing members (46, 48) or simultaneously articulatable first and second acquisition members each having a tapered, atraumatic, distal tip, and where the system includes a handle (57) and an actuation mechanism (66).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 66, 68, 69, 71, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (5,542,949). Yoon discloses the invention substantially as claimed. Yoon discloses, in col. 3, lines 33-55 and col. 5, line 59 to col. 6, line 36, a method of manipulating tissue comprising positioning a distal end of an elongate main body (89) which defines a main lumen therethrough, such that first and second acquisition members (46, 48) are positioned adjacent to tissue to be acquired, acquiring a tissue region with the acquisition members, and approximating the tissue region (with at least one clip), where acquiring the tissue region can include a vacuum created in the first acquisition member (86 or 88), where the acquisition members are articulated passively (via outer cams 120 and 122) or actively with a proximally located position control (64, 66). However, Yoon does not disclose that the tissue is within a hollow body organ. Nevertheless, Yoon discloses that his invention is used for endoscopic or laparoscopic surgery. Such surgery is commonly done within hollow organs. Thus, it would have been a matter of design choice to apply Yoon's invention to a hollow organ. The choice would be dependent upon the therapeutic demands of a hollow organ

requiring tissue manipulation.

Allowable Subject Matter

5. Claims 50-65 are allowed.

6. Claims 3-5, 7-9, 11, 12, 14-21, 24, 25, 27-32, 35-49, 67, 70, and 73-78 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a tissue acquisition and fixation system including, inter alia, a tissue acquisition device with an elongate main body defining a main lumen therethrough, where the distal end of the acquisition device is adapted to acquire tissue, and a tissue fixation device having an articulable cartridge adapted to be advanced through the main lumen, where the device comprises a flexible shaft, where a first acquisition member is articulatable via an actuation rod disposed along a length of the main body, where first and second acquisition members are individually articulatable, where each acquisition member include at least one opening positionable in offset apposition to one another, where each acquisition member comprises a tensioning member and hinge member, where the acquisition members are adapted to rotate into an offset configuration, where the distal end of the acquisition device is positioned with a guidewire, where the main body is actively or passively curved, where the handle includes a gasket, where the main body comprises a plurality of adjacent links, where the two opposing members are

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adapted to flex via a plurality of pivots, where the handle is adapted to deploy a plurality of staples from the cartridge assembly, and where the cartridge assembly comprises a stapler housing and an anvil. The prior art also does not teach or fairly suggest a method of acquiring and affixing tissue with the system, where, inter alia, the elongate main body has a first acquisition member that is articulated to acquire tissue, which is brought into contact with a tensioning member, and where the tissue is folded and affixed via cartridge assembly which is adapted to maintain a predetermined orientation relative to the main lumen of the elongated main body. The prior art does not teach or fairly suggest a method of manipulating tissue from within a hollow body organ with the system, where, inter alia, an acquisition member is advance transorally, where at least one portion of the main body is articulated by inserting a curved stylet within the main body or curving at least one portion of main body.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Julian W. Woo
Primary Examiner

November 8, 2005